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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,370	06/18/2007	Michel Dreano	SCHIAFFONATI 1	8192
1444 7590 02/26/2009 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			EXAMINER MERTZ, PREMA MARIA	
			ART UNIT 1646	PAPER NUMBER
			MAIL DATE 02/26/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/583,370	Applicant(s) DREANO ET AL.	
	Examiner Prema M. Mertz	Art Unit 1646	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 12 February 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: _____.
- Claim(s) objected to: _____.
- Claim(s) rejected: 19,21-23,25,28,31,32,40,41,43-46,48,50,53-55 and 57-62.
- Claim(s) withdrawn from consideration: 33-36.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Prema Mertz/
Primary Examiner

Continuation of 3. NOTE: The 35 USC 112, first paragraph, scope of enablement rejection over claims 19, 21-23, 25, 28, 31-32, 40, 41, 43-46, 48, 50, 53-55, 57-62, is being maintained for reasons of record as set forth in pages 3-8 of the previous office action of 5/1/08 and pages 3-5 of the previous office action of 9/12/08. Applicants argue that the present claims are not directed to preventing liver cirrhosis but rather are directed to treating liver cirrhosis regardless of what factors caused the disease. However, contrary to Applicants arguments, the instant specification is only enabling for treatment of chemical cirrhosis and not for immune hepatitis or other autoimmune liver disease.

Claims 19, 21-23, 25, 28, 31-32, 40-41, 43-46, 48, 50, 53-55, 57-62, are rejected under 35 U.S.C. 103(a) as being unpatentable over Kovalovich et al. (2001). Applicants argue that Kovalich does not teach treating liver injury with IL-6, Kovalovich

describes previous studies where pretreatment with IL-6 prior to CCl₄-induced injury and apoptosis protected against liver injury (page 26605, near the bottom of the right column), Kovalovich's own experiments use a pretreatment of IL-6 20 minutes prior to intraperitoneal injection with Jo-2 mAb (an agonistic antibody to the Fas receptor which directly causes hepatic injury by stimulating the apoptotic cell death program) to determine if IL-6 exerts its protective effect on the liver through modulation of the apoptotic cell death program (page 26606, left column, first

full paragraph, and sentence bridging pages 26606 and 26607), and therefore, accordingly, Kovalovich is not directed to treating with IL-6 after cirrhosis induced by CCl₄ (pretreatment is not the same as treatment after the occurrence of disease). However, contrary to Applicants arguments, if Kovalich taught treating liver cirrhosis with IL-6 after the occurrence of the disease, this rejection would be a 35 USC 102(b) rejection rather than a 35 USC 103(a) rejection. Therefore, the teachings in Kovalovich render obvious the instant invention.